

PTO/SB/21 (09-04)

**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

1103

Application Number

10/559,752 ✓

Filing Date

December 6, 2005

First Named Inventor

ANDRE LIEBER

Art Unit

1648

Examiner Name

Unassigned

Attorney Docket Number

016336-002700US

**ENCLOSURES (Check all that apply)**☐

Fee Transmittal Form

☐

Fee Attached

☐

Amendment/Reply

☐

After Final

☐

Affidavits/declaration(s)

☐

Extension of Time Request

☐

Express Abandonment Request

☒

Information Disclosure Statement

(2 pgs)

☐

Drawing(s)

☐

Licensing-related Papers

☐

Petition

☐Petition to Convert to a  
Provisional Application☐Power of Attorney, Revocation  
Change of Correspondence Address☐

Terminal Disclaimer

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Request for Refund

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After Allowance Communication to TC

☐Appeal Communication to Board  
of Appeals and Interferences☐Appeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)☐

Proprietary Information

☐

Status Letter

☒Other Enclosure(s) (please identify  
below):

Return Postcard

PTO/SB/08A and PTO/SB/08B (4 pgs)

References 3-46 (1097 pgs)

☐Certified Copy of Priority  
Document(s)☐Reply to Missing Parts/ Incomplete  
Application☐Reply to Missing Parts  
under 37 CFR 1.52 or 1.53

Remarks

The Commissioner is authorized to charge any additional fees to Deposit  
Account 20-1430.**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name

Townsend and Townsend and Crew LLP

Signature

Printed name

Neil G. Miyamoto

Date

March 15, 2006

Reg. No.

50,370

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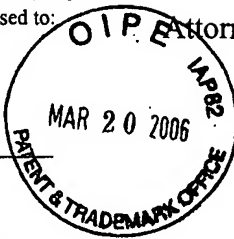
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3/15/06

TOWNSEND and TOWNSEND and CREW LLP

By:

Anthony J. Marshall



PATENT  
Attorney Docket No.: 016336-002700US  
Client Reference No.: 3784P.1US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

ANDRE LIEBER, ET AL.

Application No.: 10/559,752

Filed: December 6, 2005

For: CAPSID-MODIFIED  
ADENOVIRUS VECTORS AND  
METHOD OF USING THE SAME

Examiner: Unassigned

Art Unit: 1648

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
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Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Applicant also cites commonly owned copending U.S. Patent Application 09/980,564 (Attorney Docket No. 016336-004610, filed November 30, 2001, published as WO 00/73478 enclosed herewith) which is directed to related subject matter. Copies of non U.S. Patent references 3-46 are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Neil G. Miyamoto  
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60708856 v1



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/559,752
				Filing Date	December 6, 2005
				First Named Inventor	ANDRE LIEBER
				Art Unit	1648
				Examiner Name	Unassigned
Sheet	1	of	4	Attorney Docket Number	016336-002700US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-5,543,328	08-06-1996	McClelland, et al.	
	2	US-2003/0175243	09-18-2003	Legrand, et al.	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	3	WO	94/10323	A1	05-11-1994	Spooner, et al.		<input type="checkbox"/>
	4	WO	95/16048	A2	06-15-1995	Mittal, et al.		<input type="checkbox"/>
	5	WO	95/26412	A1	10-05-1995	Curiel, et al.		<input type="checkbox"/>
	6	WO	96/26281	A1	08-29-1996	Wickham, et al.		<input type="checkbox"/>
	7	WO	00/70071	A1	11-23-2000	Bout, et al.		<input type="checkbox"/>
	8	WO	00/73478	A2	12-07-2000	Lieber, et al.		<input type="checkbox"/>

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	9	Alemany, et al., CAR-binding ablation does not change biodistribution and toxicity of adenoviral vectors, Gene Ther. Sep;8(17):1347-53 (2001)	<input type="checkbox"/>	
	10	Bernt, et al., The effect of sequestration by nontarget tissues on anti-tumor efficacy of systemically applied, conditionally replicating adenovirus vectors, Mol. Ther. 8:746-55 (2003)	<input type="checkbox"/>	
	11	Chiu, et al., Structural analysis of a fiber-pseudotyped adenovirus with ocular tropism suggests differential modes of cell receptor interactions, J. Virol. 75:5375-80 (2001)	<input type="checkbox"/>	
	12	Chroboczek, et al., The sequence of adenovirus fiber: similarities and differences between serotypes 2 and 5, Virology. Dec;161(2):549-54 (1987)	<input type="checkbox"/>	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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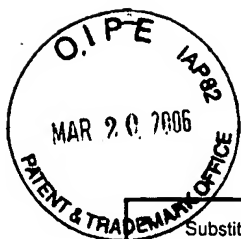
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	13	Dechecchi, et al., Heparan sulfate glycosaminoglycans are involved in adenovirus type 5 and 2-host cell interactions, Virology, 268, 382-90 (2000)	<input type="checkbox"/>
	14	Fawell, et al., Tat-mediated delivery of heterologous proteins into cells, Proc. Natl. Acad. Sci. USA 91:664-68 (1994)	<input type="checkbox"/>
	15	Gaggar, et al., CD46 is a cellular receptor for group B adenoviruses, Nat. Med. 9:1408-12 (2003)	<input type="checkbox"/>
	16	Gao, et al., Human adenovirus type 35: nucleotide sequence and vector development, Gene Ther. 10:1941-49 (2003)	<input type="checkbox"/>
	17	Graham, et al., Characteristics of a human cell line transformed by DNA from human adenovirus type 5, J Gen Virol. Jul;36(1):59-74 (1977)	<input type="checkbox"/>
	18	Herisse, et al., Nucleotide sequence of adenovirus 2 DNA fragment encoding for the carboxylic region of the fiber protein and the entire E4 region, Nucleic Acids Res. Aug 25;9(16):4023-42 (1981)	<input type="checkbox"/>
	19	Higginbotham, et al., The release of inflammatory cytokines from human peripheral blood mononuclear cells in vitro following exposure to adenovirus variants and capsid, Hum Gene Ther. Jan 1;13(1):129-41 (2002)	<input type="checkbox"/>
	20	Krasnykh, et al., Genetic targeting of an adenovirus vector via replacement of the fiber protein with the phage T4 fibrin. J. Virol. 75:4176-83 (2001)	<input type="checkbox"/>
	21	Leopold, et al., Fluorescent virions: dynamic tracking of the pathway of adenoviral gene transfer vectors in living cells, Hum. Gene Ther. 9:367-78 (1998)	<input type="checkbox"/>
	22	Lieber, et al., The role of Kupffer cell activation and viral gene expression in early liver toxicity after infusion of recombinant adenovirus vectors, J. Virol. 71:8798-807 (1997)	<input type="checkbox"/>
	23	Liu, et al., The role of capsid-endothelial interactions in the innate immune response to adenovirus vectors, Hum. Gene Ther. 14:627-43 (2003)	<input type="checkbox"/>
	24	Micheal, et al., Addition of a short peptide ligand to the adenovirus fiber protein, Gene Therapy 2:660-68 (1995).	<input type="checkbox"/>

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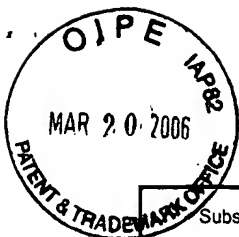
<b>Substitute for form 1449A&amp;B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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	25	Mizuguchi, et al., Adenovirus vectors containing chimeric type 5 and type 35 fiber proteins exhibit altered and expanded tropism and increase the size limit of foreign genes, Gene Feb 20;285(1-2):69-77 (2002)	<input type="checkbox"/>	
	26	Nakamura, et al., Reduction of natural adenovirus tropism to the liver by both ablation of fiber-coxsackievirus and adenovirus receptor interaction and use of replaceable short fiber, J. Virol. 77:2512-21 (2003)	<input type="checkbox"/>	
	27	Raper, et al., Fatal systemic inflammatory response syndrome in a ornithine transcarbamylase deficient patient following adenoviral gene transfer, Mol. Genet. Metab. 80:148-58 (2003)	<input type="checkbox"/>	
	28	Raper, et al., A pilot study of in vivo liver-directed gene transfer with an adenoviral vector in partial ornithine transcarbamylase deficiency, Hum. Gene Ther. 13:163-75 (2002)	<input type="checkbox"/>	
	29	Reddy, et al., Development of adenovirus serotypes 35 as a gene transfer vector, Virology 311:384-93 (2003)	<input type="checkbox"/>	
	30	Roelvink, et al., The coxsackievirus-adenovirus receptor protein can function as a cellular attachment protein for adenovirus serotypes from subgroups A, C, D, E, and F, J. Virol. 72:7909-15 (1998)	<input type="checkbox"/>	
	31	Roelvink, et al., Identification of a conserved receptor-binding site on the fiber proteins of CAR-recognizing adenoviridae, Science 286: 1568-71 (1999)	<input type="checkbox"/>	
	32	Sakurai, et al., Characterization of in vitro and in vivo gene transfer properties of adenovirus serotype 35 vector, Mol Ther. Nov;8(5):813-21 (2003)	<input type="checkbox"/>	
	33	Schiedner, et al., A hemodynamic response to intravenous adenovirus vector particles is caused by systemic Kupffer cell-mediated activation of endothelial cells, Hum Gene Ther. Nov 20;14(17):1631-41 (2003)	<input type="checkbox"/>	
	34	Shayakhmetov, et al., Efficient gene transfer into human CD34 <sup>+</sup> cells by a retargeted adenovirus vector, J. Virol. 74:2567-83 (2000)	<input type="checkbox"/>	
	35	Shayakhmetov, et al., Dependence of adenovirus infectivity on length of the fiber shaft domain, J. Virol. 74:10274-86 (2000)	<input type="checkbox"/>	

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	36	Shayakhmetov, et al., Targeting of adenovirus vectors to tumor cells does not enable efficient transduction of breast cancer metastases, Cancer Res. 62:1063-68 (2002)	<input type="checkbox"/>	
	37	Shayakhmetov, et al., The interaction between the fiber knob domain and the cellular attachment receptor determines the intracellular trafficking route of adenoviruses, J Virol. 77(6):3712-23 (2003)	<input type="checkbox"/>	
	38	Shayakhmetov, et al., Binding of Adenovirus Fibers Knob to Blood Coagulation Factors Mediates CAR-Independent Liver Tropism, Mol. Ther. 7:S165 (2003)	<input type="checkbox"/>	
	39	Smith, et al., Adenovirus serotype 5 fiber shaft influences in vivo gene transfer in mice, Human Gene Therapy 14:777-87 (2003)	<input type="checkbox"/>	
	40	Stone, et al., A Helper-Dependent Adenovirus Vector System Based on Group B Serotype 11, Mol. Ther. 7:S192 (2003)	<input type="checkbox"/>	
	41	Varnavski, et al., Preexisting immunity to adenovirus in rhesus monkeys fails to prevent vector-induced toxicity, J. Virol. 76:5711-19 (2002)	<input type="checkbox"/>	
	42	Vigne, et al., Genetic manipulations of adenovirus type 5 fiber resulting in liver tropism attenuation, Gene Ther. 10:153-62 (2003)	<input type="checkbox"/>	
	43	Vogels, et al., Replication-deficient human adenovirus type 35 vectors for gene transfer and vaccination: efficient human cell infection and bypass of preexisting adenovirus immunity, J. Virol. 77:8263-71 (2003)	<input type="checkbox"/>	
	44	Worgall, et al., Innate immune mechanisms dominate elimination of adenoviral vectors following in vivo administration, Hum. Gene Ther. 8:37-44 (1997)	<input type="checkbox"/>	
	45	Wu, et al., Flexibility of the adenovirus fiber is required for efficient receptor interaction, J. Virol. 77:7225-35 (2003)	<input type="checkbox"/>	
	46	Xia, et al., Crystal structure of the receptor-binding domain of adenovirus type 5 fiber protein at 1.7 Å resolution, Structure Dec 15;2(12):1259-70 (1994)	<input type="checkbox"/>	

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